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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,793

03/23/2007

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069818-3600

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22428 7590 06/23/2009
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EXAMINER

GREENE, IVAN A

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

06/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,793

Applicant(s)MOLENAAR, MARIKE JOANNA
BERNADETTE**Examiner**

IVAN GREENE

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-49 is/are pending in the application.
- 4a) Of the above claim(s) 32-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-31 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/23/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Claims 17-49 are currently pending. Claims 32-48 have been withdrawn based upon Restriction, discussed below. Claims 17-31 and 49 are presented for examination on the merits.

Restriction

Applicant's election with traverse of Group one in the reply filed on 04/21/2009 is acknowledged. The traversal is on the ground(s) that the alleged special technical feature, "an intact protein fraction in an amount of 8.2-11 g/100 mL", is not taught by the cited reference and is therefore novel over said reference; and no search burden exists. This is not found persuasive because while the reference (TROUP WO 2004/026294, See office action dated 03/17/2009) does not disclose an "intact protein" in the amount claimed by Applicant, the amount of "protein" is disclosed and "intact protein" would have been considered an obvious variant of "protein" therefore the instantly claimed invention as a whole would have been obvious over TROUP and therefore lacks an inventive step. As to the claimed lack of search burden, the argument is moot because "search burden" is in regard to U.S. Restriction practice only (i.e. there is no search burden requirement to establish "lack of unity of invention").

The requirement is still deemed proper and is therefore made FINAL.

Claims 32-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable

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generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/21/2009.

Information Disclosure Statement

The information disclosure statement(s) submitted on 03/23/2007 was filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Priority

The U.S. effective filing date has been determined to be 04/08/2005, the filing date of the document PCT/NL05/00269. The foreign priority date has been determined to be 04/09/2004, the filing date of document EP 04076132.2.

Objections

The disclosure is objected to because the words (abstract, p. 4, lines 30 and 35, p. 5, lines 1 and 4; [0030], [0031] (as published)) "demineralisation" and "demineralising" should be spelled as "demineralization" and "demineralizing". Appropriate correction is required.

The disclosure is objected to because of the following informalities: page 8 line 17 ([0043], as published) contains the phrase --The liquid should contain 7.6 g or more protein per 100--, however, there are no units give for the disclosed "per 100". Appropriate correction is required.

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Claims 17, 18, 22 and 49 are objected to because claims 17, 18 and 49 recite --demineralising-- the correct spelling is “demineralizing”; and claim 22 recites --fibre-- the correct spelling is “fiber”. Appropriate correction is required.

Claim 17 is further objected to because the claim recites --(b) an intact protein fraction in an amount of 8.2 to 11 g/100 mL-- and further recites --at least 8.2 g of intact protein per 100 mL--. Because the amended claim requires the protein fraction (b) to be an “intact protein” the second recited phrase is redundant and should be removed.

Rejections

Claim Rejections - 35 U.S.C. 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 23, 24 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claims 26-28 are rejected as being indefinite because claim 17 recites --the intact protein fraction comprises between 25 and 37 wt. % of whey proteins-- and dependent claim 26 says the “intact protein” is casein. It is unclear how the “intact protein” can be casein and comprise 25 to 37 wt. % of whey proteins. Claims 27 and 28 are rejected as being indefinite because they recite narrower ranges of casein but depend from claim 27 which recites the --protein is casein--.

3. Claims 23 and 24 are rejected as being indefinite because they recite --the protein fraction is in an amount of 8.7-12g per 100 mL--, and the range of the parent claim is

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“8.2 to 11 g per 100 mL”. It is unclear what the metes and bounds of the claimed protein fraction should be.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 17-31 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over HAGEMAN (US 2002/0142025) in view of SHIBUYA (US 5,576,303) and TANEYA (US 4,146,456).

Applicant Claims

Applicant claims a liquid complete nutritional composition suitable for feeding cachectic patients and having an energy density of at least 1.45 kcal/mL comprising: (a) a carbohydrate fraction in an amount of 17 to 29 g/100 mL; (b) an intact protein fraction in an amount of 8.2 to 11 g/100 mL; and (c) a lipid fraction, wherein at least 70 wt. % of the protein fraction comprises between 25 and 37 wt. % of whey proteins. Applicant

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further claims the carbohydrate fraction (a) comprises 15 to 45 wt. % of a non-reducing monosaccharide, a non-reducing disaccharide and/or a non-reducing trisaccharide, wherein the non-reducing disaccharide is not sucrose. Applicant further claims the non-reducing disaccharide is trehalose. Applicant further claims the protein fraction (b) comprises at least 1.0 wt. % of cystine residues. Applicant further claims the liquid composition further comprises 0.5 to 6 grams of fiber per 100 mL. Applicant further claims the protein fraction (b) comprises at least 8.6 wt. % of lysine residues, at least 2.5 wt. % of methionine residues, and at least 0.5 wt. % of cystine residues. Applicant further claims the lipid fraction is in an amount of 5.0 to 7.0 g/100 mL. Applicant further claims the carbohydrate fraction (c) comprises 18 to 23.5 g/100 mL. Applicant further claims the liquid composition having a viscosity below 50 mPa·s at a shear rate of 100 s⁻¹ and a temperature of 20 °C. Applicant further claims a powder, which upon reconstitution with water, provides the liquid complete nutritional composition, as described above.

**Determination of the scope
and content of the prior art (MPEP 2141.01)**

HAGEMAN teaches an enteral food composition for clinical or dietary use comprising carbohydrates, proteins (abstract). HAGEMAN further teaches the compositions contain carbohydrates, proteins and fats ([0032]). HAGEMAN further teaches proteins may be used as amino acid sources, provided that the desired amino acids become readily available by digestion ([0025]). HAGEMAN further teaches cystine-rich proteins include dairy whey proteins and specific proteins thereof ([0025]).

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HAGEMAN further teaches methionine-rich proteins include casein, casinates and casein hydrolysates ([0025]). HAGEMAN further teaches the composition should comprise sufficient levels of essential amino acids such as lysine ([0031]). HAGEMAN further teaches the carbohydrates can comprise mono-, di-, oligo-, and polysaccharides, such as glucose, fructose, maltose, sucrose, fructo-, galacto- and especially gluco-oligosaccharides, starch, starch hydrolysates and the like ([0032]). HAGEMAN further teaches the proteinaceous material is in the form of proteins or peptides, especially in the form of intact proteins ([0032]). HAGEMAN further teaches Example 4 ([0050], [0051]) with an energy content of 1.50 kcal/mL; a protein content (casein/whey; 80/20) of 8.2 g/100 mL; a carbohydrate content of 16.5 g/100 mL; a fat content of 5.5 g/100 mL; and a fiber content of 0.4 g/100 mL. HAGEMAN further teaches complete enteral tube feeding composition in a spray-dried powdered form (Example 2, claim 9).

**Ascertainment of the difference between
the prior art and the claims (MPEP 2141.02)**

The difference between the rejected claims and the teachings of HAGEMAN is that HAGEMAN does not expressly teach the non-reducing sugar trehalose or demineralized milk proteins. The deficiency in the non-reducing sugar trehalose is cured by the teachings of SHIBUYA. The deficiency in the demineralized milk proteins is cured by the teachings of TANEYA.

SHIBUYA teaches the present invention relates to a energy-supplementing saccharide source and uses thereof, more particularly, to an energy-supplementing

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saccharide source essentially consisting of trehalose (1:14-17). SHIBUYA further teaches reducing saccharides such as glucose and fructose have been used for a long time as energy supplement saccharide sources (1:24-26). SHIBUYA further teaches the reducing saccharides have a relatively-poor storage stability because of their reducing power, and generally become more unstable in coexistence with other nutritives such as amino acids and vitamins (1:26-30). SHIBUYA further teaches an energy-supplementing saccharide source essentially consisting of a non-reducing saccharide source, such as xylitol, sorbitol, maltitol, lactitol, sucrose or trehalose has been in great demand (1:31-34).

TANEYA teaches demineralized cow's milk and an apparatus and method for producing demineralized cow's milk (abstract). TANEYA further teaches in the production of cow's milk powder it is desirable for the product, in its composition, to resemble human milk (1:18-19). TANEYA further teaches the content of minerals in milk used as a material of powdered milk is higher as compared to human milk and accordingly it is required to demineralize it in the production of infant milk powder (20-24).

Regarding the specific amounts of the recited carbohydrates, proteins, lipids and fiber it would have been obvious to the skilled artisan to produce a composition with the proper amounts of said ingredients such that the patient's nutritional needs would have been met. The amounts of carbohydrates, proteins, lipids and fiber in the composition clearly would have been a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would

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be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for a skilled artisan to determine the optimal amount of each ingredient to add in order to best meet the nutritional requirements of the intended patient's. Thus, in the absence of some demonstration of unexpected results from the claimed parameters, this optimization of ingredients would have been obvious at the time of Applicant's claimed invention.

Regarding the viscosity, where the claimed prior art products are substantially identical in structure or composition or are produced by identical or substantially identical processes a *prima facie* case of either anticipation or obviousness has been established. Absent evidence to the contrary the prior art composition must possess the claimed viscosity since it is substantially identical to the claimed composition. See MPEP 2112.01.

Finding of *prima facie* obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine SHIBUYA with HAGEMAN and produce the instantly claimed invention because HAGEMAN teaches a nutritional composition comprising a milk product and SHIBUYA teaches an improved milk product. One of ordinary skill in the art would have been motivated to combine SHIBUYA with HAGEMAN because the demineralized milk, taught by SHIBUYA, would

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have provided a milk product which resembles human milk and would have been suitable for infants.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine TANEYA with HAGEMAN and produce the instantly claimed invention because HAGEMAN teaches a nutritional composition comprising a carbohydrate product and TANEYA teaches an improved carbohydrate product. One of ordinary skill in the art would have been motivated to combine TANEYA with HAGEMAN because the use of trehalose, a non-reducing sugar, would have improved the stability of the product.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Conclusion

Claims 17-31 and 49 have been presented for examination on the merits. The specification is objected; claims 17, 18, 22 and 49 are objected; claims 23, 24 and 26-28 are rejected under 35 U.S.C. 112, second paragraph; and claims 17-31 and 49 are rejected under 35 U.S.C. 103(a). No claims allowed at this time.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Thursday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IVAN GREENE
Examiner, Art Unit 1619

/PORFIRIO NAZARIO GONZALEZ/
Primary Examiner, Art Unit 1621